

IFW
PCT

PATENT
Customer No. 22,852
Attorney Docket No. 4676.0183-00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
)
Chikamasa YAMASHITA et al.) Group Art Unit: 1616
)
Application No.: 10/538,837) Examiner: Alstrum Acevedo, J.H.
)
Filed: June 13, 2005)
)
For: NOVEL DRY POWDER) Confirmation No.: 5653
INAHALATION SYSTEM FOR)
TRANSPULMONARY)
ADMINISTRATION)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), applicants bring to the attention of the Examiner the documents on the attached listing. This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits for the above-referenced application.

Copies of the listed foreign and non-patent literature documents are attached.

Copies of the U.S. patent publications are not enclosed.

Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

English abstracts of the non-English documents are enclosed.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and applicants determine that the cited documents do not constitute "prior art" under United States law, applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of such documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: September 21, 2006

By: Charles E Van Horn
Charles E. Van Horn
Reg. No. 40,266

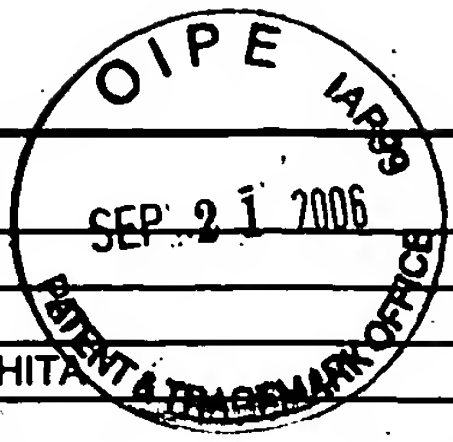


IDS Form PTO/SB/08: Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/538,837
				Filing Date	June 13, 2005
				First Named Inventor	Chikamasa YAMASHITA
				Art Unit	1616
				Examiner Name	Alstrum Acevedo, J.H.
Sheet	1	of	3	Attorney Docket Number	04676.0183-00

U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS					
Examiner Initials	Cite No. ¹	Document Number	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
		US-3,874,381	04-01-1975	Baum	
		US-4,064,878	12-27-1977	Lundquist	
		US-4,940,662	07-10-1990	Yamazaki et al.	
		US-4,992,419	02-21-1991	Woog et al.	
		US-5,044,091	09-03-1991	Ueda et al.	
		US-5,326,753	07-05-1994	Ohtsuki et al.	
		US-5,349,947	09-27-1994	Newhouse et al.	
		US-5,354,934A	10-11-1994	Pitt et al.	
		US-5,503,144	04-02-1996	Bacon	
		US-5,654,007	08-05-1997	Johnson et al.	
		US-5,752,505	05-19-1998	Ohki et al.	
		US-5,785,049	07-28-1998	Smith et al.	
		US-5,826,633	10-27-1998	Parks et al.	
		US-5,889,202	03-30-1999	Alapati et al.	
		US-5,954,047	09-21-1999	Armer et al.	
		US-5,964,416	10-12-1999	Jaeger et al.	
		US-5,996,577	12-07-1999	Ohki et al.	
		US-6,153,224	11-28-2000	Staniforth	
		US-6,186,141 B1	02-13-2001	Pike et al.	
		US-6,231,851 B1	05-15-2001	Plantz et al.	
		US-6,402,055 B1	06-11-2002	Jaeger et al.	
		US-6,497,373 B2	12-24-2002	Jaeger et al.	
		US-6,726,124 B2	04-27-2004	Jaeger et al.	
		US-2003-0101995 A1	06-05-2003	Yamashita et al.	
		US-2003-0138402 A1	07-24-2003	Yamashita et al.	

Note: Submission of copies of U.S. Patents and published U.S. Patent Applications is not required.

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
		EP 0133 767 A2	03-06-1985	The Green Cross Corporation		
		EP 0168 008 A2	01-15-1986	Takeda Chemical Industries, Ltd.		
		EP 0360340 A1	03-28-1990	Akzo N.V.		
		EP 0407276A	01-09-1991	VALOIS Société Anonyme		

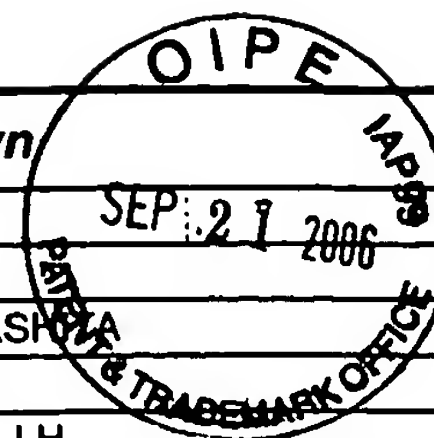


IDS Form PTO/SB/08: Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/538,837
				Filing Date	June 13, 2005
				First Named Inventor	Chikamasa YAMASHITA
				Art Unit	1616
				Examiner Name	Alstrum Acevedo, J.H.
Sheet	2	of	3	Attorney Docket Number	04676.0183-00

FOREIGN PATENT DOCUMENTS						
				dite		
		EP 0437 622 A1	07-24-1991	Kyowa Hakko Kogyo Co., Ltd.		
		EP 0578 823 A1	01-19-1994	Sumitomo Pharmaceuticals Company, Limited		
		EP 0709 085 A1	05-01-1996	Takeda Chemical Industries, Ltd.		
		WO 84/02274	06-21-1984	Hafsten		
		WO 91/16038	10-31-1991	Toray Industries, Inc.		
		WO 95/31479	11-23-1995	Inhale Therapeutic Systems, Inc.		
		WO 96/32149	10-17-1996	Inhale Therapeutic Systems		
		WO 96/40068	12-19-1996	Inhale Therapeutic Systems		
		WO 97/23239	07-03-1997	Otsuka Pharmaceutical Co., Ltd.		
		WO 99/17754	04-15-1999	Sepracor Inc.		
		WO 00/15263	03-23-2000	Rothman		
		WO 00/24444	05-04-2000	Webb		
		HU 204993B	03-30-1992	Sanyo Co.		No
		HU 205857B	07-28-1992	Nippon Kayaku KK		No
		HU 216770B	08-30-1999	Norton Healthcare Ltd		Abstract
		HU 221232B	08-28-2002	Boehringer Ingelheim GmbH		Abstract
		JU Kokai No. 60-52847	04/13/1985	Mochida Seiyaku Kabushiki Kaisha		Partial
		JP Kokai No. 3-131271	06-04-1991	Valois SA		Partial
		JP Kokai No. 06-321805	11-22-1994	Asahi Chem Ind Co Ltd		Abstract
		JP Kokai No. 8-103499	04-23-1996	Unisia Jecs Corp		Yes
		JP Kokai No. 11-171760	06-29-1999	Teijin Ltd.		Yes
		JP Kokai No. 2001-151673	06-05-2001	Nikken Chem Co Ltd		Yes

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation ⁶
		G. Slama et al., "A new non-invasive method for treating insulin-reaction: intranasal lyophilized glucagons," <i>Diabetologia</i> , 33:671-674 (1990)	
		P. Lucas et al., "Protein Deposition from Dry Powder Inhalers: Fine Particle Multiplets as Performance Modifiers," <i>Pharmaceutical Research</i> , Vol. 15, No. 4, pp. 562-69 (New York, Plenum Publishing Corp., 1998)	
		U. Conte et al., "Spray Dried Microsphere Preparation: Influence of the Technological Parameters," <i>Drug Development and Industrial Pharmacy</i> , Vol. 20, No. 3, pp. 235-58 (New York, Marcel Dekker, Inc., 1994).	
		K. Inazu & K. Shima, "Freeze-Drying and Quality Evaluation of Protein Drugs," <i>Developments in Biological Standardization</i> , Vol. 74, pp. 307-22 (Basel, Switzerland, Karger AG, 1991).	
		"Aerosol Powder Device," A partial translation of <i>Nippon Rinsho</i> , Vol. 56, No. 3 (3, 1998) p. 212 (764) left column L6 - p. 215 (767) left column L25	
		Pending Claims for U.S. Patent Application No. 10/170,339	

IDS Form PTO/SB/08: Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				<i>Application Number</i>	10/538,837
				<i>Filing Date</i>	June 13, 2005
				<i>First Named Inventor</i>	Chikamasa YAMASHITA
				<i>Art Unit</i>	1616
				<i>Examiner Name</i>	Alstrum Acevedo, J.H.
Sheet	3	of	3	<i>Attorney Docket Number</i>	04676.0183-00



Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.